

Exhibit 21

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re:)
PHARMACEUTICAL INDUSTRY) CA No. 01-12257-PBS
AVERAGE WHOLESALE PRICE) MDL No. 1456
LITIGATION) Pages 21-1 - 2-212

BENCH TRIAL - DAY TWENTY-ONE
CLOSING ARGUMENTS

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
January 26, 2007, 9:10 a.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

Page 150

1 actually is the 20 to 25 percent. I mean, you take the first
2 1992 OIG report. The spreads that Dr. Hartman is reporting
3 on are all under 30 percent?

4 THE COURT: Right.

5 MR. BERMAN: They're complaining, "What's with this
6 15 percent, what's with this 20?" They don't understand, and
7 I submit that it's not until the mid to late '90s that they
8 even understand that much of it. And in fact we saw some
9 testimony that I put up in my common slide that Congress
10 people in 2000, 2001, they still thought that most of the
11 AWP's were strict. So in this context, when you're
12 publishing --

13 THE COURT: Where was that from?

14 MR. BERMAN: That was from -- I had a spreadsheet
15 that I went through in my opening, my common opening, that
16 took us through the legislative history. They thought it
17 was -- there's lots of people who thought it was going to be
18 an average. And so the question is, did Congress ever say
19 it's okay for these folks not to publish an average? No.
20 Did they ever get approval? No. And so just because they
21 felt that they could publish this, well, where does that come
22 from? There's not a document from J & J, not one document,
23 not one memo, that says, "We got the okay because everyone
24 knows it's not an average." Nothing like that. You know, if
25 it was so widespread that everyone was okaying it, you'd

Page 151

1 think you'd find some reference to it in J & J's documents,
2 or any of these companies. Nothing, there's nothing in the
3 record that suggests that -- well, the only thing we have is
4 after-the-fact testimony that they were doing this because
5 they thought it was okay. And in fact the guidelines,
6 Johnson & Johnson's own guidelines say you can't talk about
7 the spread, you can't market the spread. It's company
8 policy. But they did it.

9 So you have the other element here, and that is,
10 they're out marketing the spread, which they don't think they
11 should be allowed to do. And in our view, it doesn't matter
12 if it's a small spread. It's an unfair practice to use the
13 spread --

14 THE COURT: So you're arguing it's the marketing of
15 the spread that makes it over the edge for J & J?

16 MR. BERMAN: Yes, yes. And, well, it's more than
17 that. Our point two, they say that we're walking away from
18 Dr. Hartman. With respect to Remicade, I don't think this
19 became clear to us until the trial how important this was,
20 but when you did have all these witnesses saying, "Look, it
21 was standard at our company to do 20 to 25 percent," and what
22 did these folks do with Remicade? They departed from that
23 standard. Assume that it's out there, that people know that.
24 And they said, "Okay, let's make ours 30 percent because we
25 want to drive more money to the doctors." That's an unfair

Page 152

1 practice.

2 Now, Mr. Cavanaugh says, "Well, you could have
3 figured that out if you got the Red Book." So what? It
4 doesn't make it fair. The only reason they bumped from
5 normal industry standard is to compete based on spread. And,
6 you know, Mr. Cavanaugh says, "Well, that's not a lot,
7 5 percent." It's \$191 million, that difference to the class,
8 just because of that 5 percent because these drugs are very
9 expensive. That's not fair.

10 Let me go right to marketing the spread. This is a
11 company that created something with respect to Remicade, the
12 Practice Management Program. It was a program in which
13 salespeople were trained to tell the doctors, to show them
14 how to make money off the spread. And they gave them a
15 financial work sheet that takes the phony AWP, let's them
16 calculate through how they can make money per patient,
17 per dose, per month; and they would take these and they would
18 train their sales folks to meet with the doctors.

19 And here's the spreadsheet that they would go over
20 with the doctors and say, "Use our drug because you can make
21 money on this margin," a margin we now know that they bumped,
22 assuming there was a standard of 25, to 30 percent. And the
23 OIG said, "You can't do this. This is exactly what we don't
24 want you doing."

25 This is from their national account manager. She

Page 153

1 says, "When you go out there, make sure you can talk to the
2 doctor about the annual profit you can make based on the
3 spread, \$2,293 a year."

4 Now, I don't care whether you call it 20 or
5 25 percent, 30 percent, it doesn't really matter. That's a
6 lot of money to consumers and third-party payors who are
7 paying these copays per doctor. And why is it fair to them
8 that they should be able to do this through a phony price?

9 This is a document that talks about -- shows you
10 how the spread marketing worked. She's reporting on a call
11 they had with the doctor, and she's explaining to them how
12 they can make \$327 off of Medicare per patient: I showed
13 them a grid showing the potential if the health plan
14 reimburses between AWP minus 5 or AWP minus 15. Dr. Kassan
15 got excited about this. We discussed safety and infection
16 rates, but they didn't seem to be an issue there. He was
17 only interested in money. And then we talked about the
18 Colorado grid, which was a grid showing how Medicare did it,
19 and he said he also liked the Medicare AWP example.

20 So, again, they're out there telling docs, "Here's
21 how you make money."

22 I submit to your Honor there's not a document that
23 shows Congress ever intended to condone this kind of
24 marketing, and in fact we know the OIG says you can't do it.
25 And we know that J & J's sister company in Exhibit 2767 says,

Page 154

1 "It's absolutely inappropriate to sell product based on the
2 difference between AWP and acquisition price." Another
3 internal document: "Under no circumstances can we talk about
4 return to practice." That's what they were doing. They were
5 violating their own standard. Mr. Cavanaugh doesn't want to
6 talk about that, but in terms of fairness, in terms of the
7 fairness of that marketing, they broke their own law and the
8 OIG law.

9 And it was no different on Procrit. This is from
10 the sales materials that were passed out at a training
11 session about Procrit, and all the materials are emphasizing
12 showing the doctor how much profit they could make, how much
13 spread they could make, the profitability of an 8 percent
14 rebate: "Know how to explain Procrit profit to the
15 pharmacist." This is all about spread marketing.

16 And in fact internally they hire McKinsey to help
17 them figure out what we should be doing in the marketplace,
18 and they say, "Look, you know, we're finding out that doctors
19 really like this. They're making \$6,000 to \$8,000 a month on
20 this one drug based on the difference between your published
21 price and your acquisition cost to the doctor." Why is that
22 fair?

23 Here's another one. This is Mr. Hess who is a
24 regional director, and he's explaining to salespeople what to
25 tell doctors. He says, "Draw out this scenario (profits) on

Page 155

1 a piece of scratch paper. Don't distribute this memo." Why
2 doesn't he want to distribute it? Because he knows it's
3 unethical to be doing this. And he's got a whole example of
4 how you show doctors how they can make money in the
5 non-Medicare context that's at the top of the page and how
6 they make money in the Medicare context, all at the expense
7 of payors. He makes it clear: "Draw it out on the scratch
8 paper. Try to explain it to them. Please do not distribute
9 this memo to your officers. Let's do it in secret." Well,
10 why do something secretly and slyly like this if you think
11 it's aboveboard, if you think it's fair?

12 In fact, they gave doctors a tool --

13 THE COURT: So you're saying, even if the spread
14 itself is not --

15 MR. BERMAN: That's right.

16 THE COURT: -- outside your speed limit, and even
17 if there was knowledge of it, it's the actual marketing
18 activity which creates the immoral conduct?

19 MR. BERMAN: In Class 2, yes. And they even gave,
20 you know, the doctors these tools. This is the Procrit
21 tool: "We want you to see that you can make money using the
22 AWP off your competitors, so just put your numbers in there,
23 put the AWP in there. We'll tell you what the cost is and
24 what the cost of the competing drug is, and you can make
25 money off of our drug."

Page 156

1 Now, that gets me back to the Remicade bump point.
2 I think I made the point, but I think it's -- I don't care
3 what Dr. Hartman said about this. I disagree with him. I'll
4 just be right up front with it.

5 THE COURT: Say it again?

6 MR. BERMAN: I don't care what Dr. Hartman said,
7 that there's a 30 percent speed limit. On Remicade, when the
8 testimony came out at trial that they bumped from 25 to
9 30 percent just to induce more profit, that, I think, is
10 unfair. There was no basis for it. It was pure gouging, and
11 I think the speed limit for Remicade should be 25.

12 THE COURT: So walk me through the slide.

13 MR. BERMAN: All right. We were questioning
14 Mr. Hoffman. Recall, your Honor, that there is a 30 percent
15 spread between WAC and AWP on Remicade. Every other drug
16 that you've heard about is 20 or 25 percent. So we asked
17 Mr. Hoffman, "Well, how did you get the 30 percent?" He
18 said, "Well, I set that number because I thought it would
19 allow doctors to make a profit, and I thought insurers would
20 pay for it."

21 THE COURT: CNTO is --

22 MR. BERMAN: Centocor. That's the J & J company
23 that markets Remicade, that sells Remicade.

24 THE COURT: So you're saying this theory came out
25 at trial?

Page 157

1 MR. BERMAN: This theory came clear at trial, yes,
2 when you heard witness after witness testify about the
3 25 percent being the standard. And all of a sudden out pops
4 Mr. Hoffman and says, "Well, we decided to depart from that
5 standard so we can drive more money to the doctors."

6 In terms of what everyone knew about the actual
7 prices --

8 THE COURT: What year did that happen in?

9 MR. BERMAN: It happened right away when they
10 started marketing. That was from the get-go. It was always
11 the 30 percent.

12 THE COURT: So you're saying that was the one
13 situation we've heard at this trial that there was an
14 adjustment to the formulaic 20 to 25 percent that people were
15 expecting?

16 MR. BERMAN: That's correct.

17 Now, Mr. Cavanaugh made a point that, you know,
18 insurers knew and understood this spread or what was
19 happening with respect to Procrit, but here we have an
20 internal memo from the director of reimbursement, and he's
21 talking about how they should explain AWP to people. And he
22 said, "Well, our strategy is not to mention --" this is
23 Centocor -- "both the wholesaler cost and AWP in the same
24 conversation because if we did so," and just skipping down to
25 the bottom line, "we would highlight spread more than we

Exhibit 22

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AVERAGE WHOLESALE PRICE) MDL No. 1456
LITIGATION) Pages 9-1 - 9-144

BENCH TRIAL - DAY NINE
BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
November 21, 2006, 9:10 a.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

<p style="text-align: right;">Page 42</p> <p>1 THE COURT: Nevertheless, I will allow this in on</p> <p>2 the issue of not the truth of the matters asserted therein,</p> <p>3 but I have to deal with statute of limitations issues, and</p> <p>4 when these people were on reasonable inquiry notice, that's</p> <p>5 still a hovering issue in the case, but it's not for the</p> <p>6 truth of it.</p> <p>7 Q. Dr. Hartman, your 30 percent expectation yardstick</p> <p>8 doesn't relate to consumers, does it? It relates to</p> <p>9 third-party payors, correct?</p> <p>10 A. That's correct.</p> <p>11 Q. Okay, now, if you look at the second page, and I'm</p> <p>12 looking at the blown-up version of the article, your Honor,</p> <p>13 right-hand column, in the first two paragraphs it talks about</p> <p>14 a sample of prices that the author of the article gathered to</p> <p>15 compare to AWP's, and he says, "This sampling showed that for</p> <p>16 single-source drugs still enjoying patent protection, such as</p> <p>17 Bristol-Myers Squibb's Taxol or Platinol, true wholesale</p> <p>18 prices are generally 10 to 20 percent below published AWP's."</p> <p>19 And then it goes on to say, "But for generic drugs, nearly</p> <p>20 every manufacturer's price was 60 percent to 85 percent below</p> <p>21 the published average wholesale price." Correct?</p> <p>22 A. Correct.</p> <p>23 Q. And 60 percent to 85 percent below the published average</p> <p>24 wholesale price is greater than 30 percent above the ASP?</p> <p>25 MR. SOBOL: Objection, your Honor.</p>	<p style="text-align: right;">Page 44</p> <p>1 comparator drugs. We've discussed survey information</p> <p>2 depicting spreads. Now let's discuss contracts. And explain</p> <p>3 to the Court what you do there. How do you use contracts to</p> <p>4 come up with your 30 percent yardstick?</p> <p>5 A. Well, excuse me, my voice doesn't wake up till noon</p> <p>6 sometimes. In looking at the contracts, I wanted to look at</p> <p>7 the behavior that was revealed through contracts, through</p> <p>8 negotiations, of what payors felt was a reasonable</p> <p>9 reimbursement, based upon what they knew, to providers.</p> <p>10 Q. So you're assuming then that payors intended to</p> <p>11 reimburse providers at or about their cost?</p> <p>12 A. I'm assuming that cost came into play and that they --</p> <p>13 they didn't enter into contract negotiations saying, "I'm</p> <p>14 want to pay you five times what it costs for you to provide a</p> <p>15 certain product to me."</p> <p>16 Q. There's nothing in those contracts that says, "We expect</p> <p>17 that your ASPs bear a relationship to the AWP's of</p> <p>18 30 percent," is there?</p> <p>19 A. Those contracts reflect negotiated terms for a variety</p> <p>20 of services, and there is some expectation that what they are</p> <p>21 being negotiated and what they're paying, if it's \$2 for this</p> <p>22 or for certain kinds of information or whatever, that it</p> <p>23 reflects some measure of cost.</p> <p>24 Q. The contracts doesn't say anything about expectations.</p> <p>25 A. What -- what would -- if one agrees to pay something, as</p>
<p style="text-align: right;">Page 43</p> <p>1 Q. Correct?</p> <p>2 MR. SOBOL: The threshold applies to --</p> <p>3 THE COURT: Overruled.</p> <p>4 MR. SOBOL: Well --</p> <p>5 THE COURT: He can say it.</p> <p>6 A. Can I now go? Okay. As I've discussed in my direct</p> <p>7 testimony, I have -- I have cited this explicitly. I've put</p> <p>8 it into the context of accumulating information. And, yes,</p> <p>9 the generic drug, there's no denying the generic spreads were</p> <p>10 larger than the single-source spreads.</p> <p>11 Q. Well, okay, let's go to your third surrogate then.</p> <p>12 THE COURT: Where is that quote? I'm trying to</p> <p>13 find it here, the page that you have highlighted.</p> <p>14 MR. EDWARDS: Oh, the page that we have, your</p> <p>15 Honor, if you look at the tab, the first four pages are the</p> <p>16 actual article. But it's difficult to read, so what we've</p> <p>17 done then after that is, we've blown up the article. And</p> <p>18 then if you look at, I guess it's the third page of the</p> <p>19 blowup, what I'm showing the witness here is two paragraphs</p> <p>20 in the right-hand column beginning with "This sampling</p> <p>21 allowed for single-source drugs --"</p> <p>22 A. And those results are summarized in my Attachment D4 for</p> <p>23 ease of reading, that range of multi-source and for single</p> <p>24 source.</p> <p>25 Q. Let's go to your third technique. We've discussed</p>	<p style="text-align: right;">Page 45</p> <p>1 a matter of revealed preference to an economist or a revealed</p> <p>2 understanding, that's saying something about what their</p> <p>3 understanding of the costs are to an economist.</p> <p>4 Q. Well, you would admit, would you not, Dr. Hartman, that</p> <p>5 payors want providers to earn a profit on drugs?</p> <p>6 A. Uhm. . . I -- I would -- I wouldn't want to -- they</p> <p>7 certainly want to keep providers in their network, and so I</p> <p>8 would take it that far.</p> <p>9 Q. And you would also admit that you have no basis for</p> <p>10 concluding that payors wanted to limit providers to a profit</p> <p>11 of no more than 30 percent per drug?</p> <p>12 A. I -- I have a -- I have the -- what I see in the</p> <p>13 contracts, I see what they're negotiating as a measure, and</p> <p>14 that is what I'm taking as a measure of their understanding</p> <p>15 of cost.</p> <p>16 Q. Well, I believe you just acknowledged that payors want</p> <p>17 to use profitability to attract providers to their network,</p> <p>18 correct?</p> <p>19 A. Payors want to keep providers in their network if they</p> <p>20 can.</p> <p>21 Q. And you haven't analyzed the impact of that objective on</p> <p>22 physician profit margins, have you?</p> <p>23 A. I haven't analyzed how much profit -- is the question,</p> <p>24 have I analyzed how much profit did a provider, a urologist</p> <p>25 or an oncologist, need to be paid to keep them in the network</p>

Exhibit 23

Attachment J.3.a: Summary of Johnson & Johnson Massachusetts Damages by Class and by Drug**Class 2: Medicare Damages to Massachusetts Third-Party Payors**

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Thru 10-06	Total	Total, Including Pre- Judgment Interest
Procrit	14,402	24,535	35,488	50,536	72,505	108,020	133,311	179,716	299,193	416,187	526,134	636,739	582,752	582,752	0	0	3,662,269	5,283,923
Remicade	0	0	0	0	0	0	0	5,941	19,095	58,337	156,715	261,870	315,105	400,694	0	0	1,217,756	1,536,951
Total	14,402	24,535	35,488	50,536	72,505	108,020	133,311	185,657	318,287	474,524	682,849	898,609	897,857	983,446	0	0	4,880,025	6,820,873

Class 3: Non-Medicare Damages to Massachusetts Consumers and Third-Party Payors

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Thru 10-06	Total	Total, Including Pre- Judgment Interest
Procrit	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Remicade	0	0	0	0	0	0	0	0	27,868	0	208,923	0	0	0	0	0	236,791	294,868
Total	0	0	0	0	0	0	0	0	27,868	0	208,923	0	0	0	0	0	236,791	294,868

Exhibit 24

Remicade WAC Spread Analysis

(NDC: 57894003001, C168J REMICADE 1PCK US PD)

	1998	1999	2000	2001	2002	2003	Total
5% Margin Analysis (25% vs. 30% above WAC)							
1. WAC (AWP / 1.3)	\$450.00	\$470.25	\$493.29	\$532.01	\$532.01	\$532.01	
2. WAC + 25% (line 1 X 1.25)	\$562.50	\$587.82	\$616.62	\$665.01	\$665.01	\$665.01	
3. WAC + 30%: Actual AWP (line 1 X 1.3)	\$585.00	\$611.33	\$641.28	\$691.61	\$691.61	\$691.61	
4. Per Unit Dollar Difference (line 3 - line 2)	\$22.50	\$23.51	\$24.66	\$26.60	\$26.60	\$26.60	
5. Units	62,790	179,721	588,606	1,311,444	2,330,501	2,802,961	7,276,023
6. Total Dollars (line 4 X line 5)	\$1,412,775	\$4,225,725	\$14,517,741	\$34,884,915	\$61,992,213	\$74,559,841	\$191,593,208
10% Margin Analysis (20% vs. 30% above WAC)							
1. WAC (AWP / 1.3)	\$450.00	\$470.25	\$493.29	\$532.01	\$532.01	\$532.01	
2. WAC + 20% (line 1 X 1.2)	\$540.00	\$564.30	\$591.95	\$638.41	\$638.41	\$638.41	
3. WAC + 30%: Actual AWP (line 1 X 1.3)	\$585.00	\$611.33	\$641.28	\$691.61	\$691.61	\$691.61	
4. Per Unit Dollar Difference (line 3 - line 2)	\$45.00	\$47.03	\$49.33	\$53.20	\$53.20	\$53.20	
5. Units	62,790	179,721	588,606	1,311,444	2,330,501	2,802,961	7,276,023
6. Total Dollars (line 4 X line 5)	\$2,825,550	\$8,451,449	\$29,035,481	\$69,769,830	\$123,984,425	\$149,119,681	\$383,186,416

Notes:

1. Units are those used in the most recent Johnson & Johnson damages analysis. All units excluded from the damages analysis are also excluded here.
2. FirstDataBank shows that the Remicade AWP is 30% above WAC. Procrit AWPs are typically 20% above WAC, but this spread increases to 25% in 2004.
3. Annual AWP is the Red Book AWP as of June 30th in each year.

Exhibit 25

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- Units are those used in the most recent Johnson & Johnson damages analysis. All units excluded from the damages analysis are also excluded here.
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- Annual AWP is the Red Book AWP as of June 30th in each year.

Plaintiffs' Exhibit

4066

01-12257-PBS

Exhibit 26

Memorandum**ORTHO BIOTECH****To:** Gary Reedy
Bill Pearson**Date:** November 7, 2000**From:** John Dempsey**cc:****Subject:** Price Increase

As per your request I have listed out the advantages and disadvantages of implementing a price increase before year end.

PRO's**CON's**

Financial—see table below	Possible backlash from media based on current public environment concerning drug pricing
Greater Discounting flexibility	Possible negative reaction from Advocacy Groups
Higher reimbursement from private payors – Possible positive perception from Physicians	BBRA could freeze Medicare AWP at current price, resulting in higher cost to physician with lower reimbursement for Medicare patients <ul style="list-style-type: none"> • Part A (APC's)—Payment currently frozen at 1999 price. This would equal a 7.4% gap • Part B — Gap could range from 3.9% to 7.4% depending on Medicare Carrier. Trailblazers of Texas has not implemented January 2000 price increase. Impacts five states—Texas, Maryland, Virginia, Delaware and District of Columbia
Price increase would equal 3.5% revenue growth	Possible negative physician reaction based on patient mix
Impact on Amgen	Cumulative Percentage increase for year 2000 would equal 7.4%
	Possible best price impact
	Selling tool for competition—Allows little time for competitive response if January launch holds true

**DEPOSITION
EXHIBIT**Hirsh 10
2/28/09**Plaintiffs' Exhibit****244**

01-12257-PBS

HIGHLY CONFIDENTIAL

MDL-OB100008374

Recommendation: Increase price on three possible dates

11/09/00

11/13/00

11/16/00

HIGHLY CONFIDENTIAL

MDL-OB100008375

Exhibit 27

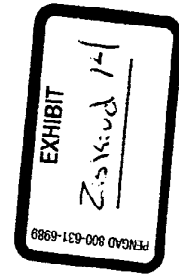
Prepared for:
Date prepared: 8/20/99

**Cost Comparison of Anti-TNF Agents in Rheumatoid Arthritis Patients
Receiving Methotrexate
for Plan and Group Managers**

		Percentage of patients weighing less than 66.7 Kg	75%
Remicade T (infliximab) Administered in Office Setting	\$611.33	Cost per vial (based on AWP)	Enbrel 0
		Average Drug Cost per treatment	\$137.50
	0%	Percentage rebate via pharmacy/PBM contract with plan	0%
		Drug cost after rebate	
	\$127	Administration services per treatment	\$0
	\$0.00	Pharmacy dispensing fee per vial	\$0.58
		Total cost per treatment	
	7	Average number of treatments per year	104
		Annual Cost	
	100%	Percentage of cost paid for by plan	100%
		Annual Cost to health plan	
Annual Per Person Savings (Cost) with Remicade			
Number of Patients Treated with Remicade			1,000
Annual Savings (Cost) per 1000 patients treated			

Enbrel
(etanercept)
Patient Self-
Administered at
Home

Page 1 of 2



MDL-CEN00024708

HIGHLY CONFIDENTIAL

Plaintiffs' Exhibit
285
01-12257-PBS

Prepared for:
Date prepared: 8/20/99

**Cost Comparison of Anti-TNF Agents in Rheumatoid Arthritis
Patients Receiving Methotrexate
for Plan and Group Managers**

Assumptions

The model examines the cost of infliximab and etanercept in rheumatoid arthritis patients receiving methotrexate. 85% of rheumatologists surveyed indicated that they would use etanercept in combination with methotrexate (Data on file at Centocor, Inc.)

AWP amounts are based on Redbook prices as of 07/15/99. Prices may not reflect actual amount paid by providers or payors.

Studies comparing safety and efficacy of infliximab and etanercept have not been performed; therefore, similarities or differences in costs cannot be used to infer comparable safety or efficacy.

Average number of infusions per year of infliximab was based on infusions over a five year period. Infliximab is administered as a 3-dose induction regimen at 0, 2 and 6 weeks followed by a q8 week maintenance regimen. Accordingly, first-year costs for infliximab will be higher than for subsequent years.

Average number of injections per year of etanercept was based on dosing twice per week.

Safety Information for infliximab for rheumatoid arthritis

In medical studies, most people had no side effects related to infliximab. Some people noticed itching or stinging of the skin and, rarely, other reactions such as chills, difficulty in breathing or low blood pressure. Some patients reported other mild side effects that did not last long such as headache, nausea, dizziness, fatigue or fever.

TNF- α mediates inflammation and modulates cellular immune response including response to infection; therefore, patients treated with infliximab may have an increased response to infection.

Please obtain full prescribing information for infliximab from your Centocor representative or at www.Centocor.com.

Remicade (TM) is manufactured by:
Centocor B.V.
Einsteinweg 101
2333 CB Leiden
The Netherlands

Remicade (TM) is distributed by:
Centocor, Inc.
200 Great Valley Parkway
Malvern, PA 19355
USA

Centocor IN99096 8/99

Exhibit 28

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re:)
PHARMACEUTICAL INDUSTRY) CA No. 01-12257-PBS
AVERAGE WHOLESALE PRICE) MDL No. 1456
LITIGATION) Pages 5-1 - 5-167

BENCH TRIAL - DAY FIVE
BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
November 14, 2006, 9:20 a.m.

LEE A. MARZILLI and TIMOTHY J. WILLETTE
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

Page 58

1 product; and also recognizing because we were introducing a
2 new service into the specialist's office that they had to
3 become comfortable with, that it was going to be financially
4 viable for them to be able to offer this service and not lose
5 money, that they had to understand what their total
6 reimbursement would be. So we took both of those factors
7 into consideration, as well as, as I mentioned --

8 THE COURT: You're trying to woo the doctor into
9 using the drug.

10 THE WITNESS: I wouldn't say woo the doctor into
11 using the drug. I would say make them comfortable that they
12 weren't going to lose money and that this was going to be
13 financially viable.

14 THE COURT: Well, did they tell you 25 percent
15 would lose money?

16 THE WITNESS: We didn't have that conversation
17 specifically with them. We did an analysis based on what we
18 thought would be appropriate. And, as I mentioned, we looked
19 at several other drugs that were in the biologics class and
20 looked at the ratio of what we believed their acquisition
21 price was for providers versus their AWP. And those ratios
22 ranged all the way up into the 40 or 50, you know, even 80
23 percent in some cases. We picked something that we thought
24 was at the reasonable, the low to middle range of that
25 survey.

Page 59

1 THE COURT: So it was primarily by looking at
2 comparables rather than doing an actual, what does it cost
3 the physician?

4 THE WITNESS: At the time of launch, yes.

5 MR. MACORETTA: You shortened up my outline
6 considerably, your Honor.

7 Q. Let's just be clear on a couple of other terms right at
8 the beginning. The AWP price, Centocor never sells any
9 Remicade at that price, right?

10 A. That's correct.

11 Q. The highest price you ever sell Remicade to anybody is
12 WAC, right?

13 A. That's correct.

14 Q. Okay. And if I were to go to a wholesaler and purchase
15 Remicade from that wholesaler, I'd buy it at WAC or something
16 very close, right?

17 A. Yes.

18 Q. So if I were to ask you what the wholesale cost of
19 Remicade was, your answer would be WAC?

20 A. WAC or something with plus or minus.

21 Q. Do you have any understanding of whether or not there
22 was any kind of retail price above that for Remicade?

23 A. Remicade really doesn't have a retail outlet because it
24 is, as you mentioned, dispensed via a physician's office. It
25 really isn't, quote/unquote, a "retail" price.

Page 60

1 Q. So looking at Exhibit 825, in, let's say, a month after
2 you launched, in October of 1998, physicians would typically
3 go to a wholesaler and buy it at somewhere around \$450 a
4 vial?

5 A. There's a range. It depends on, you know, what
6 relationship they have with the specialty distributor who
7 sold to the physician, depending on their volume of
8 purchases, et cetera, their payment terms, et cetera. I
9 don't know what exactly the price was, but --

10 Q. But they wouldn't likely be buying it for much above
11 \$450 a vial?

12 A. "Much" is a relative term.

13 Q. Five percent?

14 A. It's tough to say, given their payment terms and their
15 volume, et cetera.

16 Q. You understand that wholesalers typically work on a
17 markup of less than 5 percent, right?

18 A. First of all, let's get our terms straight here.
19 Specialty distributors are who we're talking about selling to
20 physicians. Wholesalers by contract cannot sell to
21 physicians for Remicade.

22 Q. Okay. Specialty distributors, you sell it to them at a
23 price below WAC typically, don't you?

24 A. Slightly below WAC.

25 Q. Okay. And that's because you're giving them a prompt

Page 61

1 pay discount of up to 2 percent, right?

2 A. That's correct.

3 Q. And some of those distributors are also getting
4 additional discounts for providing you with certain data,
5 correct?

6 A. Data and other services.

7 Q. What other services are you talking about?

8 A. They would provide information to the physicians. They
9 would do blast faxes. They would provide information --

10 THE COURT: What?

11 THE WITNESS: They would do blast faxes out to all
12 the physicians when --

13 THE COURT: What's that?

14 THE WITNESS: They have a mechanism where they
15 could automatically send a fax to every physician that they
16 distribute to. If we had a clinical update to our product
17 that we wanted to get the information to the physicians
18 quickly, we could hire the specialty distributors, and they
19 would send a fax out so that every physician got it
20 immediately with any kind of product updates or any other
21 information we want the physicians to get immediately related
22 to our product.

23 Q. You also understand that specialty wholesalers or
24 specialty providers were not selling Remicade to anybody at
25 AWP, right?

Page 66

1 office setting include," and could you read the last bullet
 2 point, the heading and the first sentence.
 3 A. "Expand billable services. Depending on reimbursement,
 4 office-based infusion may provide a financial benefit to a
 5 physician's practice."
 6 Q. And then it refers you to Page 8 for a financial impact
 7 work sheet, right?
 8 A. Yes.
 9 Q. Let's go to Page 8, the financial impact work sheet.
 10 And this is something that your sales rep would go over with
 11 the doctor in his office? Is that the idea?
 12 A. Our sales rep, or, more accurately, our reimbursement
 13 specialist, who provided an understanding and support to
 14 physicians to understand the logistics of getting
 15 reimbursement, coding, et cetera.
 16 Q. Well, that's right, let's talk about that for a second.
 17 Centocor had a force of sales reps who would go out and talk
 18 to the doctors, and we're talking about here
 19 gastroenterologists and rheumatologists, right?
 20 A. Correct.
 21 Q. And then in addition to the regular sales force, you had
 22 group of people called reimbursement specialists, right?
 23 A. Correct.
 24 Q. And their job was to go out and to talk to the doctor in
 25 his office in more detail about reimbursement and finance

Page 67

1 issues relating to Remicade, right?
 2 A. About office logistics and office efficiency issues, of
 3 which reimbursement and coding was a piece of it.
 4 Q. So the reimbursement specialist might sit down with the
 5 doctor or his office manager and go over what we're looking
 6 at on Page 8?
 7 A. Yes.
 8 Q. Okay. The first line of Page 8, "Sample work sheet,
 9 assumed acquisition cost," and you have typed in there
 10 "\$457 per vial," right?
 11 A. Yes.
 12 Q. So this is your rep talking to the doctor about what his
 13 cost is to purchase Remicade, right?
 14 A. It's a default number that's in the model.
 15 Q. But your reimbursement specialist is going to talk to
 16 the doctor in his office about what his cost is to purchase
 17 Remicade, isn't he?
 18 A. No. The way this was designed is, the top part is an
 19 illustrative example, as it says, a sample. The bottom, as
 20 you can see, it says "Your practice." The physician is
 21 supposed to plug in his or her own numbers there. The rep
 22 does not necessarily get involved in knowing what that number
 23 is.
 24 THE COURT: So is the representative handing out
 25 this document?

Page 68

1 THE WITNESS: They either handed it out or the
 2 physician could download it.
 3 THE COURT: All right, so you were involved in
 4 marketing directly to doctors with respect to price?
 5 THE WITNESS: We didn't set their price. We
 6 just, in terms of them understanding the financial
 7 ramifications --
 8 THE COURT: Right, but your sales team did get
 9 involved in that, right, not just the clinical aspects of the
 10 drug?
 11 THE WITNESS: They also talked about the overall
 12 financial ramifications of offering an office infusion.
 13 Q. And you said this work sheet was also available for some
 14 time on your Web site, right?
 15 A. Correct.
 16 Q. By the way, the numbers you assumed in the preprinted
 17 part at the top, if we compare that to Exhibit 825, you
 18 assumed the AWP is \$611, right? And at the time, if we look
 19 at Exhibit 825 which is your price history, when the AWP was
 20 \$611, the WAC was \$470. So your preprinted cost here for the
 21 doctor is even below WAC, right?
 22 A. In this case, yes.
 23 Q. Okay. And presumably you put that in there because you
 24 thought it was a pretty good estimate of what the doctor was
 25 going to be paying?

Page 69

1 A. I don't know why it was put in there. I wasn't there at
 2 the time.
 3 Q. And in addition to this financial impact work sheet, you
 4 also had a more detailed software program that could be used
 5 with doctors to analyze their finances and reimbursement,
 6 right?
 7 A. Yes.
 8 Q. Okay. And if you take a look at the next tab which is
 9 Exhibit 289, is it correct that this is a printout of at
 10 least part of the software program that your reimbursement
 11 specialists would use with doctors?
 12 A. I believe that's correct.
 13 Q. So in this case the reimbursement specialist would sit
 14 down with the doctor and get a bunch of input about what
 15 percent of customers were on Medicare, and what kind of
 16 private payors he billed to, and what the reimbursement rates
 17 were, right?
 18 A. Correct.
 19 Q. And that was to give the doctor a more detailed analysis
 20 of the finances of using Remicade, right?
 21 A. Of the financial ramifications of offering the service,
 22 yes.
 23 Q. And, of course, if we go back to Page 8 of the financial
 24 impact work sheet, the bottom line is the doctor's estimated
 25 monthly revenue from Remicade, right?

Page 82

1 here, your Honor. He's outside the courtroom.
 2 THE COURT: Why don't you try and finish in the
 3 next five minutes or so, and then we'll do a break till noon
 4 and then try and finish the next one by 1:00, if we could do
 5 that. Do you think we can?
 6 MR. TRETTER: The last witness lives here, but he's
 7 a former BMS employee, and I would like to get him done.
 8 THE COURT: I'm not so worried. I just don't want
 9 to hold someone from out of town. That's fine, but I don't
 10 feel the time pressure. Go ahead. Thank you.
 11 We'll get you home. Where are you from?
 12 THE WITNESS: Philadelphia, your Honor.
 13 Q. Exhibit 285, this is a printout of a computer program
 14 you used with health plans, right?
 15 A. That's correct.
 16 Q. All right. And in the printout, you're talking to the
 17 health plans about the cost of Remicade per vial, right?
 18 A. That's correct.
 19 Q. The computer program doesn't mention WAC anywhere,
 20 right?
 21 A. That's right.
 22 Q. And if we look at the second page, you have under the
 23 heading of "Assumptions," it says, "AWP amounts are based on
 24 Red Book prices as of July, 1999. Prices may not reflect
 25 actual amount paid by providers or payor." Well, there's no

Page 83

1 question that the AWP did not reflect an actual amount paid
 2 by a provider, right? We don't think any providers were
 3 buying this drug at AWP?
 4 THE COURT: What are you reading from, since it's
 5 not up on the screen --
 6 MR. MACORETTA: I'm sorry, the second page, your
 7 Honor, the second paragraph under "Assumptions."
 8 THE COURT: It just takes me a couple of seconds to
 9 get it.
 10 MR. MACORETTA: It's my fault, your Honor.
 11 THE COURT: Okay, go ahead.
 12 Q. It's correct that no providers were buying this drug at
 13 AWP; isn't that right?
 14 A. That's a reasonable assumption.
 15 Q. So as to AWP, it's not the prices may not reflect the
 16 actual amount paid by providers; it's that the prices do not
 17 reflect the actual amount paid by providers?
 18 A. If you read the whole sentence, it says providers or
 19 payors. And the reason the assumption is there is because we
 20 don't know exactly what the negotiated percent off AWP that
 21 the providers negotiated with the plans. We put an
 22 assumption in there, but it could be minus 5, minus 15,
 23 minus 17. So you have to take the sentence in its whole
 24 context.
 25 Q. The financial work sheet, the calculator we looked at

Page 84

1 earlier, you didn't show that to health plans, did you?
 2 A. No. There was really no -- the health plans are
 3 interested in what they pay the providers, which is AWP minus
 4 whatever their negotiated terms are.
 5 Q. At some point Centocor got a J-Code for Remicade; is
 6 that right?
 7 A. That's correct.
 8 Q. Okay. And a J-Code is something that Medicare uses to
 9 facilitate billing, right?
 10 A. That's correct.
 11 Q. So it's useful to the doctors who prescribe or useful
 12 for the doctors who bill for Remicade to have a J-Code
 13 specific to Remicade, right?
 14 A. It makes the reimbursement process easier.
 15 Q. Could you take a look at Exhibit 261, which is the
 16 third-from-the-last exhibit.
 17 THE COURT: So because you were single-source, are
 18 you the only drug under that J-Code?
 19 THE WITNESS: I believe so.
 20 Q. Exhibit 261, this is Centocor's application for a
 21 J-Code, correct?
 22 A. That's correct.
 23 Q. Again we're going to turn to the last page of that
 24 exhibit, your Honor, that's signed by Valerie Asbury. She
 25 was in fact the director of corporate accounts at Centocor?

Page 85

1 A. Yes.
 2 Q. In budgeting?
 3 A. Yes.
 4 Q. Okay, great. "Question 11: What is the wholesale cost
 5 of the item?" Now, could you read Centocor's answer to that
 6 question.
 7 A. "The Remicade AWP is \$585 per 100-milligram vial."
 8 Q. You told me earlier that the wholesale cost of the item
 9 is never AWP, didn't you?
 10 A. I believe what I told you earlier is that wholesaler and
 11 specialty distributors did not purchase it at AWP.
 12 Q. Didn't you also tell me that you believed that typically
 13 wholesalers sold it at some price close to WAC?
 14 A. Yes.
 15 MR. MACORETTA: That's all the questions I have
 16 right now, Mr. Hoffman.
 17 THE COURT: So this is a memo to HCFA, is that it?
 18 THE WITNESS: Yes, your Honor.
 19 THE COURT: I see. So is this a typical form you
 20 have to fill out to get Medicare reimbursement?
 21 THE WITNESS: I believe so. With the application,
 22 you have to provide the information so that they will
 23 establish the code.
 24 CROSS-EXAMINATION BY MR. CAVANAUGH:
 25 Q. If we could just stick with that document, Mr. Hoffman,

Page 90

1 BY MR. CAVANAUGH:
 2 Q. And just so we're clear, I believe what Judge Saris has
 3 just pointed out is, your retail cost wouldn't be below a
 4 wholesale cost.
 5 A. Right.
 6 Q. Let's turn to Remicade. What physician specialty treats
 7 Crohn's disease?
 8 A. Gastroenterologist.
 9 Q. When Centocor launched Remicade in 1998 for Crohn's
 10 disease, were gastroenterologists infusing drugs?
 11 A. Not to any great extent.
 12 Q. As a result, Judge Saris asked you questions about
 13 direct costs associated with infusing Remicade. Are there
 14 also capital costs for a doctor that was not infusing drugs?
 15 A. Yes.
 16 Q. Could you explain to the judge what those capital costs
 17 would entail?
 18 A. Sure. It requires a dedication of office space to set
 19 up infusion rooms, the purchase of infusion chairs, the
 20 purchase of intravenous equipment, poles, bags, supplies,
 21 et cetera. In many cases it may require the hiring of
 22 additional staff, an infusion nurse, that does not -- that is
 23 trained differently than your typical office nurse, as well
 24 as perhaps additional what I'll call back-room office staff
 25 because of the complexity of the reimbursement and the

Page 91

1 insurance coverage. And then there's also a lot of costs
 2 associated with the procurement. You probably had to buy
 3 refrigeration for storage, et cetera.
 4 Q. Now, when Judge Saris asked you questions about direct
 5 costs and you referred to a time-and-motion study, did that
 6 time-and-motion study and the numbers you provided include
 7 the capital costs that a physician would incur if he was
 8 going to undertake infusion?
 9 A. It included some of them, but not all of them. As I
 10 mentioned, we used the Government Accounting Office
 11 methodology. Some of those costs were included in the study,
 12 some of them were not.
 13 Q. And what about indirect costs? Were those included in
 14 the figure you provided?
 15 A. Once again, some of them were, some of them were not.
 16 Q. Let me -- we've had testimony in this case about copays
 17 made by patients who received Remicade or any of the other
 18 physician-administered drugs we're talking about in this
 19 case.
 20 Has Centocor looked at the level of nonpayment of
 21 copays for Remicade?
 22 A. Yes, we have.
 23 Q. And what figures have you come up with?
 24 A. Our analysis indicates that an average of about 20
 25 percent of the copays actually end up not being collected by

Page 92

1 the physicians.
 2 Q. So if a physician was looking at the cost structure for
 3 infusing Remicade, would he or she have to look at some
 4 portion of reimbursement not being received?
 5 A. Yes, a bad debt expense, if you will.
 6 Q. Did you take your bad debt expense into account in
 7 looking at the time-and-motion study?
 8 A. No. As a matter of fact, that's one of the ones that
 9 specifically was not included, because it wasn't in the GAO
 10 methodology.
 11 Q. So if we were trying to take -- when you said to the
 12 judge, if you look at all of the costs, you would have to add
 13 bad debt, additional capital expenses, as well as additional
 14 indirect expenses that weren't covered by your
 15 time-and-motion study?
 16 A. That's correct.
 17 Q. What physician specialty treats rheumatoid arthritis?
 18 A. Rheumatologists.
 19 Q. When Centocor launched Remicade for rheumatoid arthritis
 20 in 1999, were rheumatologists infusing drugs?
 21 A. Not to a great extent.
 22 Q. Had rheumatologists had any bad experiences with
 23 infusion drugs in the past?
 24 A. Yes, they did.
 25 Q. And what was that bad experience?

Page 93

1 A. They had an experience with a product called Synvisc,
 2 which was administered in the office, and they had a lot of
 3 complications with coverage from payors, with reimbursement
 4 from payors, not knowing which codes to use, et cetera, as
 5 well as, as we mentioned before, the bad debt expense. So as
 6 a result of that, many rheumatologists ended up losing money
 7 on administering that drug and decided to no longer offer
 8 that service in their office.
 9 Q. What role, if any, did that play in how Centocor --
 10 THE COURT: Was that your drug or someone else's?
 11 THE WITNESS: It was someone else's drug, your
 12 Honor.
 13 Q. That experience, what role, if any, did that play in how
 14 Centocor approached pricing for Remicade?
 15 A. We knew that -- as I mentioned in my earlier testimony,
 16 when you looked at all the components of pricing, the payor
 17 implications, but we also had to make sure that there was
 18 appropriate reimbursement for the provider in his or her
 19 office, because if that didn't exist, there was a hurdle that
 20 was going to have to be overcome, especially with the
 21 experience that the rheumatologists had, and we had to
 22 convince them that it was going to be financially viable and
 23 they weren't going to lose money on us.
 24 Q. Can Remicade also be infused in hospitals?
 25 A. Yes.

Page 102

1 greater than the percentages expressed here?

2 A. Right.

3 Q. If rebates were being --

4 A. Right, and that's why I was hesitated in answering your

5 Honor's question in that the average selling price would

6 include rebates. This is just what's going to providers.

7 THE COURT: And this is primarily hospitals.

8 MR. CAVANAUGH: Yes.

9 BY MR. CAVANAUGH:

10 Q. There's a handwritten note "and pharmacies," but is it

11 your understanding that these drugs are often administered in

12 hospitals?

13 A. Yes.

14 Q. Something like Epogen. You're familiar with Epogen,

15 right?

16 A. Yes.

17 Q. That is administered in hospitals?

18 A. And physician offices.

19 Q. And physician offices.

20 Let me -- has Centocor worked with third-party

21 payors with respect to site of care?

22 A. Yes.

23 Q. And can you explain to the judge --

24 THE COURT: Can I just go back to this document?

25 MR. CAVANAUGH: Oh, sure.

Page 103

1 THE COURT: So when you say average wholesale

2 price is the price at which wholesalers list their product,

3 this adds to the confusion. Do you have a separate meaning

4 for it within your company?

5 THE WITNESS: No. I think this -- your Honor, this

6 document is saying that AWP is basically the list -- the

7 price -- the AWP, the wholesaler, the list that the

8 wholesalers -- if you look at the Red Book and First

9 Databank, there's a WAC, which --

10 THE COURT: Wholesale acquisition cost?

11 THE WITNESS: -- is the wholesale acquisition cost,

12 and then there's the AWP.

13 THE COURT: So you understand this to mean at least

14 as what's put in the Red Book.

15 THE WITNESS: That's correct. Because the purpose

16 of this was to look at the difference between the

17 reimbursement level and the acquisition cost.

18 THE COURT: All right.

19 MR. CAVANAUGH: Your Honor, did you have any

20 further --

21 THE COURT: No.

22 MR. CAVANAUGH: Okay.

23 BY MR. CAVANAUGH:

24 Q. Let me move to a different subject, which is: Did

25 Centocor work with third-party payors with respect to the

Page 104

1 site of care for the infusion of Remicade?

2 A. Yes, we did.

3 Q. Can you explain to the judge those efforts?

4 A. Yes. A couple examples come to mind.

5 The first one was with Aetna. They had identified

6 that there was a significant amount of Remicade infusions

7 happening in the hospital and that, as I mentioned before,

8 they were significantly more costly than the physician

9 office. So they called us in and told us that as a result of

10 that, they were actually threatening to put severe

11 restrictions on Remicade access, prior authorizations,

12 et cetera. And as we discussed it with them and understood

13 what their issue was, that it was really about the hospital

14 infusions, we told them that we had the ability through

15 information that we gathered through our verification of

16 benefits service that we could identify which physicians were

17 actually referring to which hospitals.

18 And so they gave us I think it was their top ten

19 hospitals that had the highest utilization, and we came back

20 with the analysis and showed which physicians were referring

21 to the hospitals. And one of the interesting things that we

22 found in there was that in many cases, these were not

23 physicians who didn't infuse in their office. These were

24 physicians who actually did in-office infusion, but they were

25 infusing Medicare patients, they were infusing other

Page 105

1 commercial payor patients in their office, but they were

2 sending their Aetna patients to the hospital. And when Aetna

3 asked that question, they found in most cases it was because

4 the reimbursement that they were receiving from Aetna wasn't

5 adequate for them to infuse in the office.

6 MR. MACORETTA: Your Honor, I hate to object, but

7 that's all hearsay.

8 THE COURT: Sustained. Hearsay.

9 Well, actually, I'm going to take that back. I'm

10 going to sustain it as hearsay, but because state of mind is

11 part of this, I will allow it in for the corporate state of

12 mind as to why they were doing certain things. I think

13 that's the best resolution of this.

14 MR. CAVANAUGH: That's fine, your Honor.

15 THE COURT: So that's something that you heard?

16 THE WITNESS: They told us directly. Aetna told us

17 directly --

18 THE COURT: That's still hearsay, but that's

19 something that you used in your decisionmaking in pricing is

20 that fact? Why is it relevant to you?

21 THE WITNESS: It's relevant in terms of our

22 decision to work with payors to try to help them to continue

23 the support that the physician office should be the best site

24 of care from a cost perspective as well as many other

25 perspectives, and that pricing and reimbursement needed to be

Page 106

1 aligned to support making the physician office the
 2 appropriate site of care. And that affected pricing
 3 decisions, it affected reimbursement decisions.
 4 BY MR. CAVANAUGH:
 5 Q. Did you work with any other third-party payors?
 6 A. Yes, there was also High Mark, which is a regional plan
 7 in western Pennsylvania, that had a similar concern about
 8 hospital utilization. So what they did is, they took a
 9 different approach. They set up a -- basically, they moved
 10 away from the buy-and-bill model where physicians purchased
 11 the drug and then billed the health plan, and put in a
 12 managed injectable program through a specialty pharmacy, but
 13 they created an infusion fee. They worked with physicians
 14 rather and created an infusion fee that the physicians agreed
 15 upon --
 16 THE COURT: What was that?
 17 THE WITNESS: It was about between 450 and \$500 per
 18 infusion, and as a result of that, over time their hospital
 19 utilization continues to decline.
 20 THE COURT: And did you work with Aetna directly to
 21 bring patients back into the --
 22 THE WITNESS: Your Honor, this one was High Mark,
 23 which was a different one I just referred to.
 24 But on Aetna, just to close that story, once we
 25 shared with Aetna what was going on, they then took it upon

Page 107

1 themselves and they actually created a case manager. And any
 2 time a physician wanted to send a patient to the hospital,
 3 they had to go through this case manager and the case manager
 4 actually intervened and had a conversation with the physician
 5 and said, "Why do you want to send them to the hospital
 6 instead of infusing in your office?" And it's my
 7 understanding the case manager actually had authority within
 8 a range to negotiate reimbursement levels with the physicians
 9 to try to keep it in the physician office.
 10 BY MR. CAVANAUGH:
 11 Q. And you also worked with High Mark, which ultimately set
 12 an infusion fee of \$450?
 13 A. 450 to \$500, yes.
 14 THE COURT: For what?
 15 THE WITNESS: Per infusion.
 16 THE COURT: For a three-vial infusion?
 17 THE WITNESS: For a three-vial infusion, yes.
 18 BY MR. CAVANAUGH:
 19 Q. And if we looked at current reimbursement under
 20 Medicare, ASP+6, plus administration fee, how would that 450
 21 compare?
 22 A. It would be about \$300.
 23 Q. So under Medicare it would be 300, High Mark is paying
 24 450?
 25 THE COURT: Say that again.

Page 108

1 A. If you look at the total net reimbursement for Medicare,
 2 which is the difference between the ASP+6 and the acquisition
 3 cost, plus the administration reimbursement that they get on
 4 the codes, they get about \$300 for a three-vial, two-hour
 5 infusion versus the case rate that they get from High Mark,
 6 between 450 and \$500.
 7 Q. When the MMA and ASP went into effect, was there an
 8 increase in the administration fee for Remicade?
 9 A. Yes.
 10 Q. And what did it increase?
 11 MR. MACORETTA: Your Honor, object to the relevance
 12 of this. The class ends when the MMA goes into effect.
 13 THE COURT: What's the question again? I missed
 14 it. I'm looking at numbers. I'm not moving as fast as you
 15 are.
 16 MR. CAVANAUGH: I understand. When ASP went into
 17 effect, your Honor, was there an increase in the
 18 administration fee for Remicade, and your Honor has asked
 19 questions on this very subject.
 20 THE COURT: I'll allow that. That's fair.
 21 A. Yes, there was.
 22 Q. And what was that increase?
 23 A. It went from about \$60, as I referred to earlier, it
 24 went up to about \$240 and subsequently dropped down to about
 25 \$220.

Page 109

1 Q. What effect on physician reimbursement was there when
 2 you went to ASP+6 with the higher administration fee compared
 3 to the AWP reimbursement that was then in effect?
 4 MR. MACORETTA: Your Honor --
 5 THE COURT: Overruled.
 6 A. It was pretty close to a wash at the time, because the
 7 reduction in drug reimbursement was pretty much offset by the
 8 increased administration fees.
 9 Q. Have most carriers moved to ASP?
 10 A. No.
 11 Q. Of those that have moved to ASP, have they strictly
 12 followed Medicare and AWP+6?
 13 A. No.
 14 Q. What have they done?
 15 A. We've seen ranges. We've seen ASP+6, +8, +10, all the
 16 way up to +12 percent.
 17 Q. Does Centocor offer rebates to managed care
 18 organizations for Remicade?
 19 A. Yes, we do.
 20 Q. Let me show --
 21 THE COURT: Just so I can understand the dynamics,
 22 currently the physician is getting 220 for his administration
 23 costs for Remicade, is that right?
 24 THE WITNESS: That's correct.
 25 MR. CAVANAUGH: 240, your Honor.

Exhibit 29

Memo to: Jason Rubin
 From: Mike Ziskind
 Subject: New Vial Sizes
 Date: July 6, 1999

CC: Jon Cabral
 Ron Krawczyk
 Julie McHugh
 Dann Wattier

In response to your recent question, this memo provides general background on AWP and relative spread. In brief, the "spread" on most products typically ranges from 20 to 25 percent. As a matter routine this reflects the databases tendency to assume 25 percent going forward off the price to wholesalers or 20 percent going backward of "AWP" or "recommended AWP". Below, I have offered a few comments on the adequacy of the spread and factors that may influence customers perception of that spread. I also, offer comment on issues to consider when we talk about the "cost of Remicade."

Standard spreads typically structured to meet the needs of retail pharmacy and office-based markets.

Spreads of 20 to 25 percent are usually sufficient to meet the needs of retail pharmacies and physician offices. Given those spreads, pharmacies and providers will typically make between 12 and 25 percent margin, plus dispensing and administration fees as appropriate. If providers have a well-insured population and are good at collecting coinsurance, copayments and deductibles, the margin is more likely to be in the 20 to 25 percent range. If providers do a poor job a collecting from patients, they may have margins of about 5 percent, or less, depending upon the payers and payment provisions.

Infused products often have a higher than average spread.

Although spreads of 20 to 25 percent are usually sufficient to meet the needs of retail pharmacies and physician offices, infused drugs and especially biologics have often had higher spreads (e.g., IGIV products have had spreads of 40 to 60 percent.). These spreads largely reflect manufacturer sponsored pricing initiatives and payers' inability to understand or control pricing in the early 1990s. In addition, it also reflects "spread creep" as AWP has increased over time as wholesaler prices have remained steady or decreased. It is likely that the pricing activities that led to these spreads will become the subject of closer HHS OIG scrutiny (e.g., TAP Lupron).

Some home infusion companies demand higher "spreads".

When it comes to profit margins on drugs, home infusion companies represent a difficult situation. For many years, many home infusion companies had a reputation for enormous mark-ups and high profitability. This reflected their use of labor intensive infused therapies, as well as weaknesses in payers' reimbursement processes. In fact, profit

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260

01-12257-PBS

margins in excess of 100 percent for costly drugs were not uncommon into the early 1990s. As a result, payers began to negotiate aggressive discounts because there were a lot of savings to be found. In turn, home infusion companies have responded by pressing manufacturers for steep discounts so that they can maintain the profitability to which they had become accustomed.

Home infusion companies may need a higher spread than other providers because of their overhead cost structures and the time required to send staff and equipment to patients' homes. In my opinion however, home infusion companies should not be cost shifting to drugs. Instead, they should be going back to payers to negotiate appropriate payment for nursing services and equipment.

Cost varies by audience.

When Centocor discusses the cost of Remicade therapy, it is important to note that the "cost of therapy" varies widely based on the audience. For example, cost to wholesalers is less than the cost to hospitals and doctors' offices, which is usually less than the price payers reimburse. Likewise, the cost to a Kaiser Permanente organization may be less than the cost to Aetna, because Kaiser may purchase directly from wholesalers, whereas insurers may be paying based on AWP or charges.

Therefore, when we discuss the cost of therapy and when the cost of Remicade is compared to other treatment options, it is important to understand the audience's perspective. For example, if we were to routinely use cost to wholesalers we would set payers' expectations too low. If we were to routinely use AWP, we might scare off some providers who are concerned about acquisition cost. My recommendation is to adopt some standard description so that the audience knows what "cost" is being cited. I would not, however, include both cost figures in the same presentation because that may highlight spread more than we would like, even though our spread is well in the range of other infused drugs.

* * * * *

Jason, I hope this has been helpful. Please call me at extension 6008 if you have any questions.

M./Zickind/AWP Rubin Question.doc

Exhibit 30



ORIGINAL

November 5, 1998

C. Kaye Riley, HCPCS Coordinator
Health Care Financing Administration
C5-08-27
7500 Security Blvd.
Baltimore, Maryland 21233-1850

Dear Ms. Riley:

I am pleased to submit the enclosed application for an alpha-numeric code in the Health Care Financing Administration Common Procedure Coding System (HCPCS) for Remicade™ (infliximab), a breakthrough drug for the treatment of Crohn's disease.

Remicade™ is indicated for the treatment of moderately to severely active Crohn's disease or the reduction of the signs and symptoms, in patients who have an inadequate response to conventional therapy. It is also indicated as a treatment for patients with fistulizing Crohn's disease for reduction in the number of draining enterocutaneous fistula(s).

Following an expedited review, Remicade™ was approved by the FDA on August 24, 1998 and became available for wholesale purchase on October 5. Rapid and widespread adoption is expected of this new drug by gastroenterologists and other physicians who treat patients with Crohn's disease. To date, there have been 85 Medicare orders written for Remicade™. Therefore, I have included in the application a request for the assignment of a temporary code to be used pending approval of a new code for use beginning January 1, 2000.

A temporary code will facilitate claims processing and reduce the administrative burden with J3490 "Unclassified drugs". Specifically, a temporary code will eliminate the unnecessary and costly submission by physicians and review by carriers of written documentation regarding the drug administered, the dosage, the route of administration and the charge.

If you have any questions or require any additional information, please do not hesitate to contact me. In particular, if there is anything missing that would preclude consideration of the application at your next HCPCS meeting I would appreciate hearing from you as soon as possible.

I look forward to working with you on the development of the temporary and permanent codes needed to promptly and accurately report the use of this important advance in the treatment of Crohn's disease.

Sincerely,


Valerie Asbury, Director
Centocor, Inc.

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261
01-12257-PBS

Centocor, Inc. • 200 Great Valley Parkway • Malvern, Pennsylvania 19355-1307 • Telephone (610) 651-6000 • Facsimile (610) 651-6100

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Health Care Financing Administration
Common Procedure Coding System (HCPCS)
Alpha-Numeric Coding Recommendation Format

Submitted by Centocor, Inc.
November 4, 1998

INFORMATION SUPPORTING CODING MODIFICATION RECOMMENDATION

1. Item trade/brand name: **REMICADE™**
Generic name: **Infliximab**
FDA Classification: **Chimeric (Human Murine) Monoclonal Antibody to Tumor Necrosis Factor (BB-IND 5389/ODA 95-924)**

2. Describe the item in general terminology.

Description

Remicade is indicated in the treatment of patients with Crohn's disease, a chronic and debilitating disorder of the gastrointestinal tract that can greatly affect a patient's quality of life. The chronic inflammation of Crohn's disease is attributed to an imbalance between pro- and anti-inflammatory mediators. Pro- and anti-inflammatory mediators called cytokines regulate inflammation in Crohn's disease. Tumor necrosis factor- α and other pro-inflammatory cytokines predominate in Crohn's disease, resulting in chronic mucosal inflammation. Crohn's disease is neither medically or surgically curable. The goal of treatment is to induce and maintain remission, maintain quality of life, and minimize the toxicity of therapy.

Indication

REMICADE is indicated for treatment of moderately to severely active Crohn's disease or the reduction of the signs and symptoms, in patients who have an inadequate response to conventional therapy. It is also indicated as a treatment for patients with fistulizing Crohn's disease for reduction in the number of draining enterocutaneous fistula(s).

Action

REMICADE is the first of a new class of agents that blocks activity of a key biologic response mediator called tumor necrosis factor alpha (TNF- α). It is believed that REMICADE reduces intestinal inflammation in patients with Crohn's disease by binding to and neutralizing TNF- α on the cell membrane and in the blood and by destroying TNF- α producing cells. This action may explain why REMICADE is a particularly effective inhibitor of TNF- α and why REMICADE has a rapid and substantial clinical benefit.

Dosage and Route of Administration

The recommended dose of Infliximab is 5 mg/kg given as a single intravenous infusion for treatment of moderately to severely active Crohn's disease in patients who have had an inadequate response to conventional therapy. In patients with fistulizing disease, an initial 5 mg/kg dose should be followed with additional 5mg/kg doses at 2 and 6 weeks after the first infusion.

How Supplied

Remicade (infliximab) lyophilized concentrate for injection is supplied individually-boxed single-use vials in the following strength: NDC 57894-030-01, 100 mg infliximab in a 20-ml vial.

3. Why are the current code categories inadequate to describe the item?

There are no current code categories that describe this item. Remicade™ is the first anti-TNF inhibitor to receive FDA approval.

Health Care Financing Administration
Common Procedure Coding System (HCPCS)
Alpha-Numeric Coding Recommendation Format

Submitted by Centocor, Inc.
November 4, 1998

4. List any local codes used by any third party payor to process the item.

We are unaware of any local codes in use by third party payers.

5. If specific codes are not being used, how are you currently billing for the item.

Code J3490 *Unclassified drugs* is being used. In addition, documentation of the drug administered, the dosage, route of administration and charge is submitted with the claim.

6. How long has this item been on the market?

Remicade™ was commercially available October 5, 1998.

The review timetable is listed below:

- December 30, 1997: Infliximab application submitted
- May 28, 1998: FDA voted unanimously to recommend approval of infliximab
- June 30, 1998: FDA issues a Complete Review letter for infliximab
- August 24, 1998: Centocor receives approval for Remicade™ from the FDA
- October 5, 1998: Product available for wholesaler purchase

➤ Although a time span of 6 months has not elapsed since the approval of Remicade™, Centocor is requesting with this application, that Remicade™ be granted a temporary J-code. Clinical data accumulated over the past 5 years was substantial enough for the FDA to grant Remicade™ an expedited review, resulting in product approval. Remicade™ is the first agent in its class (anti-TNF inhibitor) to be approved by the FDA. In addition, Remicade™ is the only FDA approved therapy for the treatment of Crohn's Disease.

7. How are you currently marketing this product or service?

Centocor sells direct to wholesalers and specialty distributors. Remicade™ is distributed nationally through these vendors.

8. Are Medicare carriers currently paying for this item?

Initial claims are just beginning to be filed. Discussions with Medicare carriers suggest that this product will be covered since Remicade™ is the only FDA approved therapy for Crohn's disease.

9. What is the total Medicare, medicaid and private business annual volume in sales and or rental for the six months of marketing experience prior to submitting the request for coding consideration? (Do not estimate or provide projections - the information provided must represent actual volume of sales for the drug/product for the specific period of time indicated.)

Six months worth of data is not available. However, between October 5 and November 3, 1998 eighty-five (85) Medicare orders for Remicade™ have been received.

10. Of the volume identified in #9, what is the percent of use in the following settings?

Health Care Financing Administration
Common Procedure Coding System (HCPCS)
Alpha-Numeric Coding Recommendation Format

Submitted by Centocor, Inc.
November 4, 1998

- Physician office
- Ambulatory Care Clinic
- Patient Home
- Inpatient Facility
- Other

(Based on discussions with clinicians, Remicade™ will be predominantly delivered as an outpatient infusion, either in the physician office or other ambulatory site; infusion center, endoscopy suite, or hospital outpatient department.)

11. What is the wholesale cost of the item?

Remicade™ AWP: \$585.00 per 100mg vial

12. What is the retail cost of the item?

Remicade™ List Price: \$450.00 per 100mg vial

13. List any manufacturers or suppliers of similar items.


None

14. Identify the difference between this item and that of competitors.

There are no competitors for Remicade™. Remicade™ is the first agent in its class (anti-TNF inhibitor) to be approved, and the only agent approved by the FDA for use in Crohn's disease.

Recommendation submitted by:

Valerie Asbury, RN, BSN
Director, Corporate Accounts
Centocor, Inc.
200 Great Valley Parkway
Malvern, PA 19355-1307
Phone: (610) 651-6551
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Valerie Asbury, Director, Corporate Accounts

11/4/98

Date